REMARKS

In response to the above-referenced Office Action claim 8 has been rewritten to delete the word "exclusively", without prejudice, and to add the designation of claim 9 as "original". A marked up copy and a clean copy of these claims are attached.

In the above-referenced Office Action the Examiner rejected claim 8 considering the word "exclusively" as new matter. While Applicant does not agree with the Examiner in view of the fact that it does not literally appear in the specification that word has been deleted from the claims. It is noted that the main claim is closed in any event. A reconsideration and withdrawal of that rejection is requested.

The Examiner rejected the claims under 35 USC 112 in view of the fact that the Examiner considers that there is no clear indication of the amount or lipids intended to be treated or the effect to be achieved.

In answer thereto, attached is a copy of an article from the March 2002 issue of Pharmacy Times, pages 65-80. Also attached is a 2 page excerpt from the Internet entitled "Mayo Clinic Health Information High Blood Cholesterol", and a second 2 page excerpt from the Internet also entitled "Mayo Clinic Health Information High Blood Cholesterol". These examples all discuss what would constitute normal cholesterol levels, and the treatment of levels over normal. It is submitted that one of ordinary skill in the art would know what an excessive blood lipid level is and it would be obvious that the treatment of such excessive level would be directed towards normalization.

The Examiner further noted that prescription drugs often become "non-prescription, over the counter" drugs upon expiration of a patent. In the case of treatment of blood lipid levels Applicant is not aware of any such case, and to the contrary, the side effects noted by treatment of certain prescription drugs including statins is currently under scrutiny by the FDA. While such prescription drugs are effective in many cases, it is necessary because of possible side effects that such administration be done by a physician and one of ordinary skill in the art would consider this to be the case.

Concerning the word "excessive" as described in the Mayo Clinic Health Information the "desirable ranges for cholesterol levels vary depending on risk factors such as your age, gender, family history and health condition". Clearly an evaluation of these risk factors determines what is excessive, but as noted in the Pharmacy Times article the evaluation of such risk factors is well known to those of ordinary skill in the art and can be calculated even by a pharmacist. Accordingly, it is submitted that the word "excessive" would not be considered indefinite by one of ordinary skill in the art.

The Examiner has further rejected the claims as obvious under 35 USC 103 citing 5 references. The Examiner has taken the position that the Schlacter et al. patent teaches the use of a food supplement comprising fish oil, niacin and soy lecithin as a diet supplement. The Examiner relies upon the Hoie reference for use of a soy bean preparation in combination with fish oil, and the other ingredients as disclosed with fish oil described in Burr et al., inositol hexanicotinate described in Cochran et al. and lecithin described in Kirschmann et al.

It is respectfully requested that this rejection be reconsidered and withdrawn for the following reasons:

In general, the Examiner is selecting bits and pieces from the various references, without a teaching for the combination thereof. It is also submitted that the only means for making the combination involves the use of hindsight based upon Applicant's own disclosure. The Examiner's attention is directed to the case of *Panduit Corp. v. Dennison Manufacturing Co.* 1 USPQ2d 1593, 1605 (CAFC 1987). That case involved a remand from the U.S. Supreme Court in which the Court of Appeals for the Federal Circuit reaffirmed its reversal of the District Court conclusion that the invention was obvious under 35 USC 103. In addition the Court held the issue of obviousness results in a conclusion of law and not fact. The Court then found that the District Court did not treat the claims at issue as a whole, "but selected bits and pieces from prior patents that might be modified to fit its legally incorrect interpretation of each claim". Although the District Court considered 6 patents none "suggested all the claims structural limitations". The Court, in another case, stated "when prior art references require selective combination ... to render obvious a subsequent invention, there must be some reason for the combination other than hindsight gleaned from the invention itself". *Uniroyal Inc. v. Rudkin-Wiley Corp.* 5 USPQ2d 1434, 1438 (CAFC 1988).

It is submitted that this is exactly the situation presented in the instant case.

The Examiner has concluded it would be obvious to modify the food supplement of Schlater et al. for use in the treatment of excessive blood lipid levels. However, there is no reference in the Schlater et al. patent to treatment of blood lipid levels with the preparations described. Furthermore, Schlater et al. clearly requires a two phase treatment wherein product A is administered in the morning and product B administered at night. Not only are the ingredients described required, but both phases are also

required by the teachings of this reference. Therefore, it is not correct to conclude that the reference teaches the claimed method of treatment. There is no teaching in Schlater et al. for deleting, for example, unsaturated fatty acids from phase A and phase B. There is also no teaching in Schlater et al. for eliminating a number of the ingredients including amino acids and trace metals. As discussed in the specification in Schlater et al., these compounds are required and therefore could not be eliminated. There is therefore no teaching in this patent for selecting bits and piece from the disclosure and concluding that the dietary supplement could be so modified as to be effective in the treatment of high blood lipid levels. It is emphasized that we are dealing with a method of treatment, and not a composition.

Concerning the Hoie reference, the Examiner has indicated that Hoie teaches the use of fish oil concentrates and nicotinic acid derivatives. These ingredients are described as optional and not required. More importantly however the patent is directed to the use of soy protein, a photoestrogen compound, and dietary fibers. These compounds are all required and cannot be eliminated from the combination described in the patent. The fact that individually nicotinic acid derivatives and fish oil derivatives are known to be active in reducing blood lipid levels does not mean that there is a teaching in the prior art for the combination described and claimed in the instant application and independent claim 8. Similarly, the Cochran patent requires the combination of a hormone, an amino acid, and an enzyme or vitamin with at least one mineral. While the patent does describe inositol hexanicotinate, as in the case of the other references, there is no teaching for eliminating what are regarded by the inventor in those patents as essential ingredients.

Finally the Burr et al. reference does teach the effectiveness of fish oil, but makes no mention of the additional ingredients described and claimed in this application.

It is respectfully submitted that the overall teachings of each of these references cited by the Examiner must be considered on the issue of whether one of ordinary skill in the art would obviously select a single ingredient from each one without a teaching to do so. This invention is not directed to a pharmaceutical preparation but rather a method of treatment with a combination of over the counter medicines which reduce cholesterol levels. Accordingly, the compounds which make up the method of this invention are therefore admittedly known.

For example, the Kirschmann et al. teaches that linoleic acid is "necessary for the utilization of saturated fats and cholesterol", and that "[t]he other fatty acids are essential but can be synthesized from linoleic acid so long as numerous vitamins and minerals are present". Furthermore, the reference describes "one of these fatty acids is also needed for the production of lecithin. The reference teaches that lecithin breaks down cholesterol and fats in the blood, and further that nutrients "vital for the production of lecithin are choline, inositol, vitamin B 6, and magnesium". The article also teaches the combination of linoleic acid and lecithin, and the production of the same in the human body. Linoleic acid is no part of the instant invention, and as noted above, the combination with the other compounds described in claim 8 is not described.

Accordingly, reconsideration and withdrawal of this rejection is requested.

Applicant considers this case in condition for allowance and an early notice thereof is respectfully requested.

Respectfully submitted,

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